DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

WARNING LETTER
CIN-WL-8534

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 17, 2001

Stanley Huckaby, President
Huckaby Pharmacal, Inc.
6316 Old LaGrange Rd.
Crestwood, KY 40014-9461

Dear Mr. Huckaby:

During a recent inspection of a contract drug manufacturer, FDA determined that you distribute the prescription drug product Stagesic-10. This product is manufactured under contract by Pharmakon Labs, Inc., Tampa, Florida, for distribution by your firm Huckaby Pharmacal, Inc., Crestwood, KY, under your own private label. The product contains Hydrocodone Bitartrate, a controlled substance, and is promoted in the package insert for moderate to moderately severe pain.

Based on the above claims this product, Stagesic-10, is a drug within the meaning of Section 201(g)(1) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug, and Cosmetic Act, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drug.

Further, the article of drug, Stagesic-10, is misbranded in that its labeling fails to bear adequate directions for the use for which the article is represented or suggested (as described above), and it is not exempt from this requirement under regulation 21 CFR 201.115, since the article is a new drug within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for this drug.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. It is further your responsibility as a private label distributor to assure that products you distribute have been reviewed and approved by the FDA, where such approval is required.

You should take prompt action to correct all these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the U.S. Food and Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, Attention: Charles S. Price, Compliance Officer.

Sincerely,

Deborah Greiko
for Henry L. Fielden

Director, Cincinnati District